

premises used in the preparation of biological products.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

§ 117.4 Test animals.

(a) All test animals shall be examined for clinical signs of illness, injury, or abnormal behavior prior to the start of a test and throughout the observation period specified in the test protocol.

(b) All animals used for test purposes shall be identified either collectively or individually in a manner conducive to an accurate interpretation of the results of the test.

(c) No test animals shall be given a biological product during the pre-conditioning period which would affect its eligibility according to the test requirements. No treatment, with a biological product or otherwise, shall be administered to a test animal during a test period which could interfere with a true evaluation of the biological product being tested.

(d) During the course of a test, animals that are injured or show clinical signs of illness or unfavorable reactions that are not due to the test may be removed from the test and treated or humanely destroyed. If sufficient animals do not remain for the test to be evaluated, the test shall be declared inconclusive and may be repeated.

(e) Test animals that show clinical signs of illness that are due to the test may be treated or humanely destroyed if the illness has progressed to a point (defined in the filed Outline of Production) when death is certain to occur without therapeutic intervention. When interpreting the results of the test, the animals that were treated or humanely destroyed because of illness due to the test and the animals that have died from illness due to the test prior to being humanely destroyed shall be combined into a common statistic of mortality due to the test.

[38 FR 15499, June 13, 1973, as amended at 60 FR 43356, Aug. 21, 1995]

§ 117.5 Segregation of animals.

Animals which have been infected with or exposed to a dangerous, infectious, contagious, or communicable

disease shall be kept effectively segregated at a licensed establishment until such time as they are humanely destroyed or successfully treated and removed as healthy animals.

§ 117.6 Removal of animals.

Production animals or ex-test animals which are no longer useful at the licensed establishment may be removed from the premises of the licensed establishment; provided, such removal is accomplished in a manner as shall preclude the dissemination of disease and in accordance with the following conditions:

(a) Meat-producing animals which received a biological product containing inactivated microorganisms and adjuvants within 21 days shall not be removed; or

(b) Animals which received virulent microorganisms within 30 days shall not be removed; or

(c) Only animals that are in a healthy condition as determined by a veterinarian shall be removed, except as provided in paragraph (d) of this section.

(d) Other animals that are injured or otherwise unhealthy, except when affected with a communicable disease, may be removed for immediate slaughter to an abattoir operated in accordance with the Federal Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act of 1967, 81 Stat. 585 (21 U.S.C. sec. 601 et seq.): *Provided*, That such animals shall be properly marked for identification and the inspector in charge of slaughter operations is given due notice in advance.

(e) All animals on the premises shall be disposed of in accordance with the provisions of the regulations in this part and where specific provision is not made therefor shall be disposed of as required by the Administrator.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

PART 118—DETENTION; SEIZURE AND CONDEMNATION

Sec.

118.1 Administrative detention.

118.2 Method of detention; Notifications.